

MAR 21 2006

F. 510(k) Summary

Applicant: Stick Tech Ltd, PO Box 114, 20521 Turku, Finland
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Contact Person: Karri Airola, Ph.D.

U.S. Agent to respond to: William M. Troetel, Ph.D.

FDA requests: 80 Parkway West
Mount Vernon, NY 10552
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wtroetel@westnet.com

Date Prepared: January 30, 2006

Device Trade Name: everStick® A&O

Device Common Name: Glass fiber for orthodontic splinting

Device Classification Name: Orthodontic Plastic Bracket
(21 CFR §872.5470)

Description of Device:

everStick® A&O is a semi-manufactured product made of glass fibers and polymer/resin matrix. The glass fiber in everStick® A&O is unidirectional which increases the strength and stiffness of the final product perpendicular to the direction of the fibers.

Intended Use: For orthodontic splinting

everStick A&O is substantially equivalent to its predicate device Damon 3 (510(k) number K052477) byOrmco Inc. in its clinical use. The composition of everStick® A&O is equal to everStick® PERIO (510(k) number K030072). By comparing the clinical usage of everStick A&O with the plastic bracket Damon 3 and by comparing the ingredients of everStick® A&O to the existing data available from dental polymerizable material, it can be stated that everStick® A&O does not expose the dentist nor the patient to unacceptable risks.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAK 21 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stick Tech Limited
C/O Dr. William M. Troetel
Certified Regulatory Consultant Managing Partner
William M. Troetel, LLC
80 Parkway West
Mount Vernon, New York 10552

Re: K051953
Trade/Device Name: everStick[®] A&O
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW
Dated: March 7, 2006
Received: March 8, 2006

Dear Dr. Troetel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and


Radiological Health

Enclosure

B. Indications for Use Statement510(k) Number (if known): K051953Device Name: everStick® A&O

Indications for Use:

- For orthodontic splinting


Susan Russo, General Hospital,
General Services
K051953

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ____
(Optional Format 1-2-96)